

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

ALLSTATE INSURANCE COMPANY
and ALLSTATE PROPERTY AND
CASUALTY INSURANCE COMPANY,

Plaintiffs

v.

TOTAL TOXICOLOGY LABS, LLC;
MARTIN BLUTH, M.D.; SCOTT P.
ZACK, D.C.; and CORY J. MANN,

Defendants.

Civil Action No. _____

DEMAND FOR JURY TRIAL

COMPLAINT

Plaintiffs Allstate Insurance Company and Allstate Property and Casualty Insurance Company (hereinafter, "Allstate" and/or "plaintiffs"), by their attorneys, SMITH & BRINK, hereby allege as follows.

I. INTRODUCTION

1. This is a case about a clinical urine drug testing laboratory and its managers/operators who engaged in a scheme to defraud Allstate by submitting false and fraudulent insurance claims through the U.S. Mail seeking reimbursement under the Michigan No-Fault Act, Mich. Comp. Laws § 500.3101, *et seq.*, for urine drug testing services that were never performed, were medically

unnecessary, and were submitted using fraudulent billing practices and fake diagnoses.

2. Defendants Total Toxicology Labs, LLC (“Total Toxicology”); Martin Bluth, M.D. (“Bluth”); Scott Zack, D.C. (“Zack”); and Cory J. Mann (“Mann”) (collectively, the “defendants”) each conspired to, and did in fact, defraud Allstate by perpetrating a healthcare billing fraud scheme in violation of state and federal law.

3. Total Toxicology purports to provide urine drug testing services to referring providers whose patients are being prescribed medication (1) to ensure that the provider’s patients are complying with their medication regime and/or (2) to ensure that the provider’s patients are not abusing their prescription medication or illicit drugs.

4. In reality, the defendants actively sought to generate as many referrals as possible regardless of the reason for the referral and without a determination from the treating provider that each urine drug test performed was necessary for each patient.

5. Bluth, Total Toxicology’s Chief Medical Officer, submitted letters to Allstate falsely attesting to the medical necessity for the testing allegedly performed by Total Toxicology. *See Exhibit 1.*

6. Zack is Total Toxicology’s President and Chief Financial Officer.

7. Upon information and belief, Zack, by and through an entity under his control, has an ownership interest in Total Toxicology.

8. Mann manages Total Toxicology.

9. Upon information and belief, Mann, by and through an entity under his control, has an ownership interest in Total Toxicology

10. The managers and operators of Total Toxicology, including Bluth, Zack, and Mann, conspired to develop a systematic plan that enabled Total Toxicology to submit claims to Allstate for urine drug testing that was medically unnecessary and fraudulently billed.

11. The purpose of the defendants' scheme was to exploit the benefits available under the Michigan No-Fault Act by generating as many bills as possible by doing (or purporting to do) as much urine drug testing as possible.

12. To this end, the defendants engaged in a number of improper practices to maximize referrals, including the use of standing orders, panel preferences, and preprinted forms that ignored questions of medical necessity in favor of preselecting as many urine drug tests as possible.

13. After it received a urine specimen, Total Toxicology billed Allstate for confirmatory urine drug testing that was not necessary and was done in violation of the established standard of care in the clinical laboratory community.

14. Total Toxicology also utilized fraudulent billing practices, including unbundling.

15. The defendants used scare tactics to drive up the number of referrals submitted to Total Toxicology.

16. For example, the medical necessity letter signed by Bluth states that “[p]hysicians can be held liable for patients misusing or abusing prescription drugs” and that “[i]f the DEA feels that a physician who [sic] is not properly managing the distribution of controlled substances, they can shut down a physician’s practice, and take away a physician’s license, or even prosecute in extreme cases.” *See Exhibit 1.*

17. The defendants also added diagnoses to their bills that were not made by the patient’s treating provider, but were fraudulently made by the defendants to facilitate payment to them.

18. Billing for services that are not medically necessary for each patient’s care, recovery, or rehabilitation is prohibited under the Michigan No-Fault Act.

19. Allstate reasonably relied on Total Toxicology’s bills to contain truthful and accurate representations regarding the urine drug testing allegedly performed and the necessity for the same.

20. Total Toxicology exploited its superior knowledge of esoteric laboratory practices and billing and took advantage of Allstate’s lack of familiarity

with the same to bill Allstate for urine drug tests that were never performed and/or were unnecessary.

21. Abusive laboratory practices, including non-patient-specific testing and the use of preprinted forms that encourage excessive testing, have been condemned.

22. The federal government, for example, has expressly stated that it holds laboratories responsible for unnecessary testing and does not allow laboratories to blame excessive urine drug testing on the referring provider.

23. Millennium Health, LLC f/k/a Millennium Laboratories, Inc. (“Millennium”), a competitor to Total Toxicology in the urine drug testing market, recently agreed to pay the government almost a quarter of a billion dollars to resolve very similar allegations that preprinted forms were utilized to facilitate unnecessary testing, including the use of standing order forms and testing panels.

See Exhibits 2 and 3.

24. Standing orders and panel preferences were responsible for more than 90% of the total urine drug testing at issue in this Complaint.

25. All of the defendants’ actions described throughout this Complaint were undertaken intentionally.

26. The insurance fraud scheme executed by the defendants was designed to, and did in fact, result in payment of No-Fault proceeds from Allstate to Total Toxicology for the benefit of each and all of the defendants named herein.

27. In each claim at issue in this Complaint for which Allstate is seeking damages, an Allstate automobile insurance contract was the platform upon which the defendants perpetrated their fraudulent scheme.

28. By this Complaint, and as detailed in each count set out below, Allstate brings this action for: (1) violations of the federal Racketeer Influenced and Corrupt Organizations (RICO) Act, 18 U.S.C. § 1962(c) and (d); (2) common law fraud; (3) civil conspiracy; (4) payment under mistake of fact; and (5) unjust enrichment.

29. Allstate's claim for compensatory damages include: (1) payments made by Allstate to Total Toxicology in reliance upon the defendants' false representations that Total Toxicology was eligible to receive reimbursement under the Michigan No-Fault Act; (2) payments made by Allstate to Total Toxicology in reliance upon the false medical documentation submitted, or caused to be submitted, by the defendants; (3) treble damages; (4) statutory interest; (5) costs, including, but not limited to, the costs of claims handling and the cost of investigation to uncover the fraudulent scheme executed by the defendants; and (6) attorney's fees.

30. By this Complaint, Allstate also seeks a declaration pursuant to 28 U.S.C. § 2201 that Total Toxicology has no right to receive payments from Allstate for any pending and previously-denied claims for urine drug testing services that were not reasonably necessary and/or were not properly billed.

31. As a result of the defendants' fraudulent billing scheme detailed herein, Allstate has paid in excess of \$15,802 to Total Toxicology since 2015.

II. THE PARTIES

A. PLAINTIFFS

32. Allstate Insurance Company and Allstate Property and Casualty Insurance Company are corporations duly organized and existing under the laws of the State of Illinois.

33. Allstate Insurance Company and Allstate Property and Casualty Insurance Company have their principal places of business in Northbrook, Illinois.

34. At all times relevant to this Complaint, Allstate was authorized to conduct business in Michigan.

B. DEFENDANTS

1. Total Toxicology Labs, LLC

35. Total Toxicology Labs, LLC is a limited liability company formed under the laws of the State of Michigan.

36. Upon information and belief, Zack maintains an ownership interest in Total Toxicology through a holding company.

37. At all times relevant to this Complaint, Total Toxicology conducted business in Southfield, Michigan.

38. At all times relevant to this Complaint, Total Toxicology purportedly performed urine drug testing on specimens that were collected from patients insured under Allstate policies, including those patients identified in Exhibit 4.

2. Martin H. Bluth, M.D.

39. Martin H. Bluth, M.D. is a resident and citizen of the State of Michigan.

40. Bluth is a licensed medical doctor in the State of Michigan.

41. Bluth is the Chief Medical Officer at Total Toxicology.

42. As part of his duties as the Chief Medical Officer, Bluth (falsely) represented to Allstate that testing performed at Total Toxicology was medically necessary.

43. Bluth's medical necessity letters were sent to Allstate via the U.S. Mail.

44. As Total Toxicology's Chief Medical Officer, Bluth benefitted from Total Toxicology's wrongful receipt of Michigan No-Fault proceeds from Allstate.

3. Scott P. Zack, D.C.

45. Scott P. Zack, D.C. is a resident and citizen of the State of Florida.
46. Zack is a licensed chiropractor in the State of Michigan.
47. Upon information and belief, Zack, by and through an entity under his control, has an ownership interest in Total Toxicology.
48. Zack is the current President and Chief Financial Officer of Total Toxicology.
49. As Total Toxicology's President, Chief Financial Officer, and owner, Zack benefitted from Total Toxicology's wrongful receipt of Michigan No-Fault proceeds from Allstate.

4. Cory J. Mann

50. Cory J. Mann is a resident and citizen of the State of Michigan.
51. Upon information and belief, Mann, by and through an entity under his control, has an ownership interest in Total Toxicology.
52. Mann manages Total Toxicology.
53. As Total Toxicology's manager and owner, Mann benefitted from Total Toxicology's wrongful receipt of Michigan No-Fault proceeds from Allstate.

III. JURISDICTION AND VENUE

54. Subject matter jurisdiction over this action is conferred upon this Court by 28 U.S.C. §§ 1331 and 1332.

55. Supplemental jurisdiction over the plaintiffs' state law claims is proper pursuant to 28 U.S.C. § 1367.

56. Allstate is a citizen of the State of Illinois for purposes of 28 U.S.C. § 1332.

57. Total Toxicology is domiciled in the State of Michigan for the purposes of 28 U.S.C. § 1332.

58. Bluth is a resident and citizen of the State of Michigan.

59. Zack is a resident and citizen of the State of Florida.

60. Mann is a resident and citizen of the State of Michigan.

61. Further, the amount in controversy, exclusive of interest and costs, exceeds \$75,000, the sum set forth in 28 U.S.C. § 1332.

62. Venue is proper pursuant to 28 U.S.C. § 1391(b)(2) whereas a substantial part of the events giving rise to the claims at issue herein occurred within the Eastern District of Michigan.

IV. MICHIGAN'S NO-FAULT ACT

63. Allstate underwrites automobile insurance in Michigan.

64. Michigan's No-Fault Act provides for the payment of unlimited medical and rehabilitative benefits on a first-party payor basis for injured victims of motor vehicle accidents. Mich. Comp. Laws § 500.3107(1)(a).

65. Personal protection insurance benefits are payable for “[a]llowable expenses consisting of all reasonable charges incurred for reasonably necessary products, services, and accommodations for an injured person’s care, recovery, or rehabilitation” arising out of a motor vehicle accident. Mich. Comp. Laws § 500.3107(1)(a).

66. “Under [the No-Fault] statutory scheme, an insurer is not liable for any medical expense to the extent it is not a reasonable charge for the particular product or service, or if the product or service itself is not reasonably necessary.” Nasser v. Auto Club Ins. Ass’n, 435 Mich. 33, 49 (1990).

67. A claimant who seeks to hold an insurer liable for No-Fault benefits has the burden of proving that the service claimed is reasonably necessary and that the charge for the service is reasonable. Id.

68. Claims for personal injury benefits under the No-Fault Act are available only if the benefits are for “accidental bodily injury” and only if those injuries “arise[e] out of” or are caused by “the ownership, operation, maintenance or use of a motor vehicle . . .” Mich. Comp. Laws § 500.3105(1).

69. Subject to limited exceptions, an insurer must pay each claim for personal protection insurance benefits arising out of a motor vehicle accident within thirty (30) days after receiving “reasonable proof of the fact and of the amount of the loss sustained.” Mich. Comp. Laws § 500.3142(2).

70. The Michigan No-Fault Act provides that “[a] physician, hospital, clinic or other person or institution” may only charge a “reasonable amount” for personal injury protection (PIP) benefits for treatment/services which have been “lawfully render[ed]” to an injured person who has sustained bodily injury in an automobile accident. Mich. Comp. Laws § 500.3157.

71. “If the treatment was not lawfully rendered, it is not a no-fault benefit and payment for it is not reimbursable.” Cherry v. State Farm Mut. Auto. Ins. Co., 195 Mich. App. 316, 310 (1992).

72. The Michigan No-Fault Act provides that an insurer “may be allowed by a court an award of reasonable sum against a claimant as an attorney’s fee for the insurer’s attorney in defense against a claim that was in some respect fraudulent or so excessive as to have no reasonable foundation.” Mich. Comp. Laws § 500.3148(2).

73. As alleged in this Complaint, the defendants violated Michigan’s No-Fault Act by submitting, or causing to be submitted, bills to Allstate seeking reimbursement for urine drug testing that was not actually provided; was not reasonably necessary for the care, recovery, or rehabilitation of the patients at issue in this Complaint; and was fraudulently billed.

V. BILLING FOR TESTING NEVER RENDERED

74. At all times relevant to this Complaint, the defendants had a singular objective: to generate as many claims for payment as possible and to make the charges submitted by Total Toxicology as high as possible.

A. TOTAL TOXICOLOGY ONLY PERFORMS ONE TESTING PROCEDURE

75. Total Toxicology admits that its most prevalent urine drug testing methodology (LC-MS/MS) consists of a single test that is capable of generating numerous drug-specific results.

76. Indeed, according to Total Toxicology's website, "liquid chromatography tandem mass-spectrometry (LC-MS/MS), is a more specific method, and returns a quantitative analytical result. These results provide precise identification of all drugs and metabolites present or absent." *See Exhibit 5.*

77. Upon information and belief, Total Toxicology's LC-MS/MS urine drug testing methodology uses a solvent gradient for the liquid chromatography (LC) portion of the procedure.

78. The urine specimen sample is dissolved in the first solvent (the initial mobile phase).

79. The initial mobile phase carries the analytes (i.e., drugs) through the stationary phase where the drugs adhere (stick) to the stationary phase.

80. The stationary phase continues to flow, but a progressively greater proportion of a second solvent is mixed into the mobile phase until it completely replaces the original solvent.

81. The increasing gradient of the second solvent causes the analytes (drugs) to progressively detach from the stationary phase and be eluted from the column where they are introduced into the tandem mass spectrometry (MS/MS) portion of the procedure.

82. The technique of progressively changing the proportion of the two solvents in the mobile phase is known as a “solvent gradient.”

83. For example, morphine may release its attachment from the stationary phase when the ratio of the first solvent and the second solvent reaches 90:10, resulting in only the morphine analyte (drug) appearing at the end of the column while the rest of the analytes (drugs) remain.

84. As the first and second solvent continue to mix reaching a ratio of 80:20, the amphetamine analyte (drug) may then release its attachment and appear at the end of the column.

85. The process is continued until the solvent gradient no longer causes analytes (drugs) to detach from the stationary phase and be eluted from the column.

86. The only costs to Total Toxicology are the costs of the equipment, the cost of setting up the stationary phase for each urine sample, the cost of introducing the specimen into the mobile phase, the cost of automatically pumping the two solvents through the system, and the cost of reporting the results to the referring provider.

87. Because Total Toxicology must perform at least one procedure in order to conduct quantitative urine drug testing and because Total Toxicology only performs one procedure via its LC-MS/MS testing, Total Toxicology's costs are not in any way dependent on or correlated to the number of specific drugs that are tested for.

88. It makes no difference what drug tests the treating provider orders, as the same two solvents and the same analytic procedure is performed on every urine specimen.

89. All of the costs associated with Total Toxicology's LC-MS/MS testing are incurred with the testing of the first drug and there is no additional marginal cost incurred for testing each drug after the first.

90. In other words, the cost to Total Toxicology of performing LC-MS/MS urine drug testing is the same whether a referring provider requests the testing of one drug or forty drugs.

91. As such, Total Toxicology pushes its referring providers to refer for several drugs to be tested per specimen regardless of need since each subsequent drug test ordered after the first drug generates purely additional profits to the defendants.

B. BILLING FOR URINE DRUG TESTING

92. The defendants submitted reimbursement claims to Allstate through the U.S. Mail on Health Insurance Claim Forms (“HICF”) (also known as “CMS-1500” claim forms) approved by the National Uniform Claim Committee (“NUCC”) and referenced in the NUCC Instruction Manual.

93. The back of all HICF forms contains the following language in bold font: “NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.”

94. The defendants submitted reimbursement claims to Allstate containing Current Procedural Terminology (“CPT”) Codes seeking payment for urine drug testing purportedly performed on specimens received from referring providers and patients located in the State of Michigan.

95. CPT Codes are published annually by the American Medical Association (AMA) to facilitate the efficient processing of healthcare charges by insurance carriers and other private and governmental healthcare payors.

96. According to the Health Insurance Portability and Accountability Act (“HIPAA”), all healthcare providers are mandated to bill insurance carriers, including auto insurance carriers like Allstate, utilizing the HIPAA-defined standard transaction code sets (which, in the context of this Complaint, are the CPT Codes).

97. Each provider has the responsibility to select the CPT Code that accurately and truthfully identifies the services performed and the complexity involved in rendering those services.

98. The CPT Code Book details which urine drug testing billing codes are applicable when submitting a reimbursement claim seeking payment for a presumptive/qualitative urine drug screen.

99. The CPT Code Book also details the correct CPT Codes for the more specific and complex definitive/quantitative urine drug tests.

100. CPT Codes for definitive/quantitative testing are usually specific to the drug being measured in a specimen.

101. Thus, definitive/quantitative testing is almost always more expensive than presumptive/qualitative testing and results in higher reimbursement to the laboratory (Total Toxicology) because (1) presumptive/qualitative codes are ordinarily bundled and only one code is billed regardless of the number of drugs

tested while definitive/quantitative codes are billed for each individual drug tested and (2) definitive/quantitative tests have higher reimbursement.

102. If a CPT Code specific to the drug being tested for is not available, the CPT Code for the testing method used to perform the definitive/quantitative urine drug test is reported instead.

103. The CPT Code Book clearly directs laboratories not to bill the definitive/quantitative CPT Codes Total Toxicology used for reimbursement of claims where only presumptive/qualitative testing was performed.

104. The onus is on the laboratory to select the appropriate billing code based on the drug tested for or the type of urine drug test performed (i.e., presumptive/qualitative, semi-quantitative, or definitive/quantitative).

C. FRAUDULENT BILLING OF CPT CODE 83789

105. Total Toxicology billed Allstate for services not rendered every time it sought reimbursement for CPT Code 83789 as Total Toxicology did not use the testing methodology encompassed by that code.

106. CPT Code 83789 (“*Mass spectrometry and tandem mass spectrometry (MS, MS/MS), analyte not elsewhere specified; quantitative, each specimen*”) is an unspecified analyte code that can only be billed when a code for quantitative testing for the specific drug/analyte tested is not listed in the CPT Code Book and

the testing method used by the clinical laboratory is mass spectrometry or tandem mass spectrometry.

107. Total Toxicology confirms that it does not perform purely mass spectrometry or tandem mass spectrometry testing and its lab reports do not contain statements that Total Toxicology ever performed solely mass spectrometry or tandem mass spectrometry testing.

108. Instead, Total Toxicology holds itself out as a laboratory that uses the liquid chromatography-tandem mass spectrometry (LC-MS/MS) testing method. *See, e.g., Exhibit 5.*

109. As column chromatography was always part of Total Toxicology's testing methodology (i.e., the "LC" part of Total Toxicology's reported LC-MS/MS method), Total Toxicology never performed purely mass spectrometry testing and was never eligible to bill CPT Code 83789.

110. It is not appropriate for Total Toxicology to ignore the liquid chromatography portion of its alleged LC-MS/MS testing in order to bill for non-specific analytes.

111. Indeed, the CPT Code Book specifically directs providers to "[s]elect the name of the procedure or service that accurately identifies the service performed. Do not select a CPT code that merely approximates the service provided."

112. Total Toxicology's testing method does not meet the criteria identified in CPT Code 83789 and is therefore not an accurate representation of the services performed.

113. Total Toxicology, at the direction of the individual defendants, almost always billed Allstate for multiple units of CPT Code 83789 related to a single urine specimen, indicating that multiple tests were performed when in fact no testing was performed that warranted billing CPT Code 83789 (because no test was purely mass spectrometry or tandem mass spectrometry since there was a column chromatography portion).

114. Moreover, CPT Code 83789 can only be billed once per specimen, which is explicit in the AMA's definition of the code ("*Mass spectrometry and tandem mass spectrometry (MS, MS/MS), analyte not elsewhere specified; quantitative, each specimen"* [emphasis added]), and Total Toxicology almost always billed multiple units of CPT Code 83789 for a single specimen.

115. A specimen is defined as the portion of a body fluid (for example, urine or blood) that is collected from the patient (blood and urine constitute two different specimens).

116. Thus, while it was not proper for Total Toxicology to bill even one unit of CPT Code 83789 at all (because its testing methodology was never purely mass spectrometry or tandem mass spectrometry as required by the definition of

the code), every unit in excess of one unit of 83789 billed as urine drug testing is patently in violation of the CPT Code Book definition.

VI. IMPROPER RELATIONSHIP WITH REFERRING PHYSICIANS

117. The defendants relied on their connections with other Michigan providers to generate baseless and unnecessary referrals to Total Toxicology, especially Mendelson Orthopedics, P.C., inclusive of its assumed names Mendelson Kornblum Physical Therapy and Mendelson Kornblum – Orthopedic and Spine Surgeons (hereinafter referred to as “Mendelson Orthopedics”).

118. Allstate’s review of the patients at issue in this Complaint revealed that physicians associated with Mendelson Orthopedics were responsible for the referral of 77% of Total Toxicology’s patients who were insured by Allstate.

119. Put differently, almost eight (8) out of every ten (10) specimens tested by Total Toxicology is generated from a physician at Mendelson Orthopedics.

120. These high referral numbers are not surprising based on the numerous connections between Zack and Mann, on the one hand, and Mendelson Orthopedics and its physicians, on the other hand.

121. For example, Mendelson Orthopedics owns a MRI clinic called Silver Pine Imaging, LLC, which Zack and Mann manage and share in the profits.

122. Similarly, Zack, Mann, and the owners of Mendelson Orthopedics share interests in an ambulatory surgical center called Synergy Spine and Orthopedic Surgery Center.

123. A former business associate of both Zack and Mann testified that there was an “ongoing relationship” with the Mendelson Orthopedics physicians and that Zack and Mann worked with the “Mendelsons” to start Synergy Spine and Orthopedic Surgery Center.

124. The defendants used their association with physicians at Mendelson Orthopedics to ensure a steady flow of patient referrals to Total Toxicology.

125. The physicians at Mendelson Orthopedics routinely submit urine specimens to Total Toxicology as a matter of course, and without regard for necessity.

126. Thus, the relationships and numerous connections between Zack and Mann (the owners of Total Toxicology) and the Mendelson group (who account for almost all of the referrals to Total Toxicology) directly resulted in unnecessary referrals for urine drug testing, which was known to Zack and Mann.

127. Urine drug testing that is performed solely for pecuniary benefit and not based on medical necessity is not compensable under the Michigan No-Fault Act.

VII. FRAUDULENT UNNECESSARY, UNREASONABLE, AND EXCESSIVE TESTING

128. The defendants billed Allstate for a litany of urine drug testing that was medically unnecessary, unreasonable, excessive, and was not performed in accordance with established standards of care for urine drug testing.

129. The unnecessary, unreasonable, and excessive urine drug testing performed and encouraged by the defendants included (1) unnecessary confirmatory testing of expected point-of-care screening results, (2) failure to perform screening testing in the absence of point-of-care screening testing, and (3) unnecessary quantitative confirmation testing.

A. UNNECESSARY CONFIRMATORY TESTING OF EXPECTED POINT-OF-CARE SCREENING RESULTS

130. The standard of care for urine drug testing is that only unexpected screening results should be confirmed (absent extenuating circumstances that must be documented in the patient's medical records by the treating provider).

131. For example, the Substance Abuse and Mental Health Services Administration (SAMHSA), a federal agency within the Department of Health and Human Services that sets guidelines for clinical drug testing for federal programs, has stated that “[i]n clinical settings, confirmation is not always necessary. Clinical correlation is appropriate. . . . In addition, a confirmatory test may not be needed; patients may admit to drug use or not taking scheduled medications when

told of the drug test results, negating the necessity of a confirmatory test. However, if the patient disputes the unexpected findings, a confirmatory test should be done.” *See Exhibit 6.*

132. Thus, SAMHSA confirms that, at most, only unexpected initial screening results should be confirmed in the absence of a patient-specific decision otherwise from the treating provider.

133. Point-of-care testing (“POCT”) is used by providers to obtain immediate drug testing results indicating whether a patient’s specimen contains the prescribed medication, an illicit substance, and/or a non-prescribed medication.

134. In fact, most positive POCT results will be due to the medications prescribed by the provider.

135. The defendants were aware that POCT was performed by the referring provider.

136. Total Toxicology’s requisition form contains a section titled “POC Results” in which referring providers indicate the POCT results.

137. Despite the standard of care for clinical laboratories like Total Toxicology that expected screening results do not need to be confirmed, the defendants nonetheless billed Allstate for confirmatory testing of expected screening results.

138. Contrary to Bluth's medical necessity letter, sent to Allstate to falsely justify the urine drug testing performed relative to each patient listed in Exhibit 4, such universal confirmatory testing is unnecessary and excessive.

139. In clinical urine drug testing, confirmatory testing is not always done and certainly should not be done automatically.

140. Instead, confirmatory testing is to be ordered at the treating provider's discretion and must be patient-specific, e.g., when an initial screening test result is clinically unexpected for the particular patient at issue (such as when a doctor-prescribed drug is reported as negative or when a non-prescribed or illicit drug is reported as positive).

141. Absent extenuating circumstances (as found and documented by the treating provider), confirmatory testing by any methodology is not necessary where the screening test indicates that a drug is not present in the patient's urine (i.e., the test is negative).

142. In rare instances dependent on the individual patient's clinical situation, confirmatory drug testing may be medically necessary when the results of the screening test are presumptively positive or when the results of the screening test are negative and the negative finding is inconsistent with the patient's medical history.

143. However, for confirmatory testing on a negative qualitative test to be appropriate, the referring provider, and not the testing laboratory, must determine if confirmatory testing is necessary after taking into consideration all known facts at the time the sample is collected.

144. No provider can make a blanket determination across all patients and all dates of service as to what constitutes reasonable confirmatory urine drug testing in all cases.

145. Instead, the individual provider must determine the reasonableness and necessity of urine drug testing on a patient-by-patient and visit-by-visit basis.

146. Total Toxicology used excessive and unjustifiable confirmatory testing to confirm the absence of a drug that was clearly reported as “negative,” or not present, in the POCT screen performed by the treating provider.

147. For example, the level of confirmation Total Toxicology performed on the specimens of patients undergoing pain management treatment after involvement in predominately low-level motor vehicle accidents significantly exceeded the level of confirmation required by the Nuclear Regulatory Commission’s policy on drug testing confirmation.

148. Persons authorized to operate a nuclear power reactor under the scope of the Nuclear Regulatory Commission (“NRC”) are required to submit to drug

and alcohol testing as part of their continued duties. 10 C.F.R. § 26.31 (NRC's Fitness for Duty Program).

149. The NRC mandates that “[s]pecimens that yield positive initial drug test results or are determined by initial validity testing to be of questionable validity must be subject to confirmatory testing by the laboratory, except for invalid specimens that cannot be tested.” 10 C.F.R. § 26.31(d)(3).

150. The NRC defines “initial drug test” as “a test to differentiate ‘negative’ specimens from those that require confirmatory testing.” 10 C.F.R. § 26.5.

151. Thus, the NRC does not require that confirmatory testing be performed on negative screening (i.e., initial drug test) results for persons entrusted with operating nuclear reactors.

152. In comparison, Total Toxicology billed Allstate for unnecessary confirmatory testing of negative screening results for almost every claim at issue herein, all of which involve patients purportedly injured in low-level motor vehicle accidents and none of whom are known to maintain and/or operate nuclear power reactors.

153. Total Toxicology engaged in a fraudulent scheme designed to obtain payment for excessive and unnecessary confirmatory testing of expected screening test results.

154. This scheme is objectively fraudulent as it disregards established standards of care for when confirmatory testing is necessary.

155. The defendants cannot dismiss their complicity in performing excessive and unnecessary urine drug testing whereas (a) Zack and Mann knowingly used their relationship with Mendelson Orthopedics and its physicians to generate unnecessary referrals, (b) Bluth personally (and falsely) attested to the necessity of the urine drug testing, and (c) as discussed below, clinical laboratories are personally held responsible for unnecessary urine drug testing.

1. Exemplar Claims

156. The following are representative examples of the defendants' practice of billing Allstate for medically unnecessary confirmation of expected point-of-care screening results.

a. Patient W.R. (Claim No. 0334051067)¹

157. Patient W.R. presented to Mendelson Orthopedics on May 26, 2015 and purportedly gave a urine sample to Anthony Oddo, D.O. ("Oddo").

158. Oddo indicated in W.R.'s May 26, 2015 medical record that there were "[n]o medications currently" prescribed to W.R. and that "[h]is urine was appropriate."

¹ To protect the confidentiality of its insureds, Allstate hereinafter refers to each by his or her initials and Allstate claim number.

159. Mendelson Orthopedics submitted a report to Allstate via U.S. Mail detailing the POCT results of W.R.’s urine specimen. *See Exhibit 7.*

160. According to the report attached hereto as Exhibit 7, each drug/analyte tested reported a “negative” result.

161. Furthermore, Mendelson Orthopedics submitted a requisition form with W.R.’s purported urine specimen to Total Toxicology that indicated each “Medication or Drug” listed on the requisition form was tested via POCT and reported as negative. *See Exhibit 8.*

162. Oddo requested that Total Toxicology perform a comprehensive panel of testing on W.R.’s urine specimen. *Id.*

163. Total Toxicology’s comprehensive panel includes testing for twenty-five (25) medications/drugs.

164. Total Toxicology submitted a report detailing the lab results of W.R.’s urine drug testing to Allstate through the U.S. Mail. *See Exhibit 9.*

165. According to W.R.’s lab report, Total Toxicology confirmed that each of the drugs/analytes originally tested via POCT were in fact “negative,” or not present in W.R.’s urine specimen. *Id.*

166. It was not necessary for Total Toxicology to confirm the expected POCT results.

167. Nonetheless, Total Toxicology submitted a HICF to Allstate through the U.S. Mail for the quantitative confirmatory drug testing services encompassed by the following eleven (11) billing codes: 80324 (amphetamines); 80345 (barbiturates); 80346 (benzodiazepines); 80348 (buprenorphine); 80353 (cocaine); 80361 (opiates); 80349 (cannabinoids); 80359 (Methylenedioxyamphetamines (MDA, MDEA, MDMA)); 80358 (methadone); 83992 (PCP); and 80365 (oxycodone). *See Exhibit 10.*

168. As the above drugs were initially tested by the referring provider and were found to be “negative,” as evidenced by the requisition form submitted to Total Toxicology with W.R.’s urine specimen, Total Toxicology unnecessarily performed quantitative confirmation testing.

169. Allstate was billed \$995.85 relative to these eleven (11) definitive/quantitative testing CPT Codes that were unnecessarily performed to confirm expected POCT results. *Id.*

170. Total Toxicology also billed Allstate several additional billing codes corresponding to the excessive testing improperly performed pursuant to the predetermined comprehensive panel in contravention of the standard of care for clinical laboratories. *Id.*

171. Bluth submitted a signed medical necessity letter to Allstate to falsely support Total Toxicology's charges for its urine drug testing of W.R.'s urine specimen.

172. Total Toxicology and Bluth submitted claims for payment and accompanying medical records relative to W.R. to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary.

173. Allstate relied upon Total Toxicology's and Bluth's submissions in adjusting the claims.

b. Patient S.D. (Claim No. 0343247978)

174. Patient S.D. presented to Mendelson Orthopedics on March 23, 2015 and purportedly gave a urine sample to Guiseppe Paese, D.O. ("Paese").

175. Paese indicated in S.D.'s March 23, 2015 medical record that a "[u]rinary drug screen was performed on the patient today. It is consistent with her current medication regimen."

176. Mendelson Orthopedics submitted a report to Allstate via U.S. Mail detailing the POCT results of S.D.'s urine specimen. *See Exhibit 11.*

177. According to the report attached hereto as Exhibit 11, each drug/analyte tested reported a "negative" result.

178. Furthermore, Mendelson Orthopedics submitted a requisition form along with S.D.'s purported urine specimen to Total Toxicology that indicated

each “Medication or Drug” listed on the requisition form was tested via POCT and reported as negative, and that S.D. was not taking any prescribed medications. *See Exhibit 12.*

179. Notwithstanding that there was no reason to conduct additional urine drug testing, Total Toxicology billed for a comprehensive panel of testing on S.D.’s urine specimen that tested for twenty-five (25) medications/drugs. *Id.*

180. Total Toxicology submitted a report detailing the lab results of S.D.’s urine drug testing to Allstate through the U.S. Mail. *See Exhibit 13.*

181. According to S.D.’s lab report, Total Toxicology confirmed that each of the drugs/analytes originally tested via POCT were in fact “negative” or not present in S.D.’s urine specimen. *Id.*

182. It was not necessary for Total Toxicology to confirm the expected POCT results.

183. Nonetheless, Total Toxicology submitted a HICF to Allstate through the U.S. Mail for the quantitative confirmatory drug testing services encompassed by the following ten (10) billing codes: 80324 (amphetamines); 80345 (barbiturates); 80346 (benzodiazepines); 80348 (buprenorphine); 80353 (cocaine); 80361 (opiates); 80359 (Methylenedioxymphetamines (MDA, MDEA, MDMA)); 80358 (methadone); 83992 (PCP); and 80365 (oxycodone). *See Exhibit 14.*

184. As the above drugs were initially tested by the referring provider and were found to be “negative,” as evidenced by the requisition form submitted to Total Toxicology with S.D.’s urine specimen, Total Toxicology unnecessarily performed quantitative confirmation testing.

185. Allstate was billed \$936.74 relative to these ten (10) definitive/quantitative testing CPT Codes that were unnecessarily performed to confirm expected POCT results. Id.

186. Total Toxicology also billed Allstate several additional billing codes corresponding to the excessive testing improperly performed pursuant to the predetermined comprehensive panel in contravention of the standard of care for clinical laboratories. Id.

187. Bluth submitted a signed medical necessity letter to Allstate to falsely support Total Toxicology’s charges for its urine drug testing of S.D.’s urine specimen.

188. Total Toxicology and Bluth submitted claims for payment and accompanying medical records relative to S.D. to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary.

189. Allstate relied upon Total Toxicology’s and Bluth’s submissions in adjusting the claims.

c. Patient J.R. (Claim No. 0348093667)

190. Patient J.R. presented to Mendelson Orthopedics on March 1, 2016 and purportedly gave a urine sample to Theresa Richardson, PA-C (“Richardson”).

191. Richardson indicated in J.R.’s March 1, 2016 medical record that the patient “does utilize Percocet, Flexeril, and Naprosyn,” that “[t]he patient does have a medical marijuana card,” and “[p]reliminary urine drug screen is consistent with the medications that the patient is taking.”

192. Mendelson Orthopedics submitted a report to Allstate via U.S. Mail detailing the POCT results of J.R.’s urine specimen. *See Exhibit 15.*

193. According to the report attached hereto as Exhibit 15, each drug/analyte tested reported a “negative” result except for expected “positive” results for Oxycodone and THC that correspond to J.R.’s prescribed medications.

194. Furthermore, Mendelson Orthopedics submitted a requisition form along with J.R.’s purported urine specimen to Total Toxicology that indicated each “Medication or Drug” listed on the requisition form was tested via POCT and reported as negative except for the expected positive results for J.R.’s lawful prescriptions. *See Exhibit 16.*

195. Wednesday Hall, D.O. (“Hall”) is identified as the requesting provider on the requisition form submitted to Total Toxicology along with a request that testing be performed using a predetermined custom profile. Id.

196. Total Toxicology submitted a report detailing the lab results of J.R.'s urine drug testing to Allstate through the U.S. Mail. *See Exhibit 17.*

197. According to J.R.'s lab report, Total Toxicology confirmed the results already obtained via POCT.

198. It was not necessary for Total Toxicology to confirm the expected POCT results.

199. Nonetheless, Total Toxicology submitted a HICF to Allstate through the U.S. Mail for the quantitative confirmatory drug testing services encompassed by the following ten (10) billing codes: 80324 (amphetamines); 80345 (barbiturates); 80346 (benzodiazepines); 80348 (buprenorphine); 80353 (cocaine); 80361 (opiates); 80359 (Methylenedioxymphetamines (MDA, MDEA, MDMA)); 80358 (methadone); 83992 (PCP); and 80365 (oxycodone). *See Exhibit 18.*

200. As the above drugs were initially tested by the referring provider and resulted in expected findings based on the patient's medication regimen, Total Toxicology unnecessarily performed quantitative confirmation testing.

201. Allstate was billed \$1,021.74 relative to these ten (10) definitive/quantitative testing CPT Codes that were unnecessarily performed to confirm expected POCT results. *Id.*

202. Total Toxicology also billed Allstate several additional billing codes corresponding to the excessive testing improperly performed pursuant to the

predetermined comprehensive panel in contravention of the standard of care for clinical laboratories. Id.

203. Bluth submitted a signed medical necessity letter to Allstate to falsely support Total Toxicology's charges for its urine drug testing of J.R.'s urine specimen.

204. Total Toxicology submitted claims for payment and accompanying medical records relative to J.R. to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary.

205. Allstate relied upon Total Toxicology's submissions in adjusting the claims.

d. Patient C.B. (Claim No. 0353347602)

206. Patient C.B. presented to Mendelson Orthopedics on December 4, 2015 and purportedly gave a urine sample to Elaine McCallister, PA-C ("McCallister").

207. McCallister indicated in C.B.'s December 4, 2015 medical record that the patient "continues to take the Percocet four times a day" and that "a urine drug screen is performed in the office today testing positive for oxycodone."

208. Mendelson Orthopedics submitted a report to Allstate via U.S. Mail detailing the POCT results of C.B.'s urine specimen. *See Exhibit 19.*

209. According to the report attached hereto as Exhibit 19, each drug/analyte tested reported a “negative” result except for an expected “positive” result for Oxycodone corresponding to the prescribed Percocet.

210. Furthermore, Mendelson Orthopedics submitted a requisition form along with C.B.’s purported urine specimen to Total Toxicology that indicated each “Medication or Drug” listed on the requisition form was tested via POCT and reported as negative except for the expected positive result for Oxycodone. *See* Exhibit 20.

211. Hall is identified as the requesting provider on the requisition form submitted to Total Toxicology along with a request that testing be performed using a predetermined custom profile. *Id.*

212. Total Toxicology submitted a report detailing the lab results of C.B.’s urine drug testing to Allstate through the U.S. Mail. *See* Exhibit 21.

213. According to C.B.’s lab report, Total Toxicology confirmed that each of the drugs/analytes originally tested via POCT was in fact “negative” and further confirmed the presence of Oxycodone under the section of the lab report entitled “Consistent Results Reported Medication Detected.”

214. It was not necessary for Total Toxicology to confirm the expected POCT results.

215. Nonetheless, Total Toxicology submitted a HICF to Allstate through the U.S. Mail for the quantitative confirmatory drug testing services encompassed by the following ten (10) billing codes: 80324 (amphetamines); 80345 (barbiturates); 80346 (benzodiazepines); 80348 (buprenorphine); 80353 (cocaine); 80361 (opiates); 80359 (Methylenedioxymphetamines (MDA, MDEA, MDMA)); 80358 (methadone); 83992 (PCP); and 80365 (oxycodone). *See Exhibit 22.*

216. As the above drugs were initially tested by the referring provider and resulted in expected findings based on the patient's medication regimen, Total Toxicology unnecessarily performed quantitative confirmation testing.

217. Allstate was billed \$1,021.74 relative to these ten (10) definitive/quantitative testing CPT Codes that were unnecessarily performed to confirm expected POCT results. *Id.*

218. Total Toxicology also billed Allstate several additional billing codes corresponding to the excessive testing improperly performed pursuant to the predetermined comprehensive panel in contravention of the standard of care for clinical laboratories. *Id.*

219. Bluth submitted a signed medical necessity letter to Allstate to falsely support Total Toxicology's charges for its urine drug testing of C.B.'s urine specimen.

220. Total Toxicology submitted claims for payment and accompanying medical records relative to C.B. to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary.

221. Allstate relied upon Total Toxicology's submissions in adjusting the claims.

B. FAILURE TO PERFORM PRESUMPTIVE/QUALITATIVE TESTING

222. In some instances, referring providers did not perform POCT before sending specimens to Total Toxicology for urine drug testing.

223. In these instances, pursuant to the standard of care for clinical laboratories, Total Toxicology should have performed its own presumptive/qualitative testing instead of immediately performing definitive/quantitative testing, but it did not.

224. At all relevant times to this Complaint, Total Toxicology submitted charges to Allstate seeking payment for presumptive/qualitative testing relative to only five (5) dates of service.

225. This is not surprising as presumptive/qualitative testing is usually reimbursed at a lower rate than definitive/quantitative confirmatory testing per specimen.

226. At all relevant times, Total Toxicology has been, and remains, capable of performing presumptive/qualitative testing.

227. But instead of performing a presumptive/qualitative test in those instances where a screen had not already been performed at the point-of-care level to determine whether definitive/quantitative testing was warranted, the defendants instead made the deliberate decision to perform definitive/quantitative testing immediately.

228. The defendants' decision resulted in hundreds of instances where expensive and complex definitive/quantitative testing was unnecessarily performed that could have been avoided if initial testing to screen out expected results had been performed.

229. The defendants can offer no legitimate or valid reason why they did not perform presumptive/qualitative testing no sooner than March 2016.

230. Indeed, as discussed above, the standard of care in the clinical laboratory community is to conduct a presumptive test and then confirm only those drugs/drug categories where the screening result was unexpected or where the treating provider has a patient-specific reason to request confirmation of a presumptive/qualitative test result.

231. The defendants blatantly disregarded the standard of care in favor of maximizing their profits.

C. THE DEFENDANTS' PROCEDURES AND FORMS PROMOTE UNNECESSARY TESTING

232. As detailed above, the defendants had the singular goal of generating as many claims as possible against payors like Allstate and resorted to billing for services not rendered and billing for unnecessary urine drug testing to achieve this goal.

233. The defendants were aided in attaining their goal by the standard procedures and forms that they established that were used by all treating providers who referred specimens to Total Toxicology for urine drug testing, including custom profiles, panel testing, and requisition forms.

234. After a review was conducted by Allstate relating to each patient at issue in this Complaint in which Total Toxicology submitted a requisition form or otherwise identified the testing ordered, it was confirmed that more than 90% of the testing performed was based upon either a referring provider's custom profile (i.e., standing order) or a panel preference.

235. Referring providers who referred specimens to Total Toxicology were able to complete a "custom profile" form, which was kept on file with Total Toxicology.

236. Each custom profile contains several categories of drugs/analytes that will automatically be tested by Total Toxicology for every specimen.

237. The custom profile form – and the drugs/analytes to be tested contained therein – is chosen by the referring provider at the commencement of the relationship between Total Toxicology and the referring provider.

238. The custom profile form – and the drugs/analytes contained therein – is necessarily not patient-specific as it is established prior to the patient's urine drug testing referral.

239. The custom profile form remains on file with Total Toxicology and serves as the default for tests to be done by Total Toxicology unless the referring provider opts for a testing panel on the requisition form that he/she submits to Total Toxicology with each urine sample.

240. The testing panels used by Total Toxicology likewise contain a slate of drugs to be tested on a specimen that does not call for any assessment of patient-specific need.

241. A requisition (i.e., prescription) form accompanies each urine sample referred to Total Toxicology for testing.

242. Total Toxicology's use of custom profiles and panel testing also violate established standards of practice that demand that only medically necessary urine drug testing be performed, as decided on a patient-by-patient and visit-by-visit basis by a licensed healthcare professional.

243. The Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”) has formulated a compliance program providing clear guidance to clinical laboratories to reduce fraud and abuse within their organizations and “assist clinical laboratories in developing effective internal controls that promote adherence to applicable Federal and State law, and the program requirements of Federal, State, and private health plans.” *See Exhibit 23 at 45077.*

244. With respect to custom profiles and testing panels, the OIG has stated that “standing orders . . . too often . . . have led to abusive practices.” Id. at 45081; *see also* Exhibits 2 and 3.

245. Specifically, the OIG has stated that “[l]aboratories routinely offer customized profiles and panels to physicians. Physicians often order the profile/panel containing the test they need rather than specifying just the needed test(s). Profiles and panels desensitize physician concerns about the medical necessity of the laboratory tests they are ordering. Moreover, panels and profiles contribute to unbundling billing schemes and contribute to the ordering of medically unnecessary laboratory tests.” *See Exhibit 24.*

246. By way of example, phencyclidine (PCP) was tested (and billed to Allstate) without the referring provider indicating the medical necessity of testing

for such an illicit substance relative to almost 90% of the patients at issue in this Complaint.

247. With respect to requisition forms, the OIG has stated that “[t]he laboratory should construct the requisition form to ensure that the physician or other authorized individual has made an independent medical necessity decision with regard to each test the laboratory will bill.” *See Exhibit 23 at 45079.*

248. As discussed above, instead of abiding by the OIG (and other) guidelines, Total Toxicology’s requisition form instead is designed to increase the number of tests performed and ignores considerations about medical necessity.

249. This is evidenced by the default to the referring provider’s custom Provider Acknowledgment Form on file (which necessarily cannot be patient-specific as it was decided before the patient was known to the referring provider) and by the requisition form’s failure to allow the referring provider to subtract any tests from the panel preference (though the provider is given the option to add tests).

250. “Laboratory compliance programs, to be effective, should communicate to physicians that claims submitted for services will only be paid if the service is covered, reasonable, and necessary for the beneficiary, given his or her clinical condition. Laboratories should take all reasonable steps to ensure that it is not submitting claims for services that are not covered, reasonable, and

necessary for the beneficiary, given his or her clinical condition.” *See Exhibit 23 at 45079.*

251. Instead of taking steps to ensure that it was only submitting claims for necessary drug testing, Total Toxicology (by and through its officers and managers, including Bluth, Zack, and Mann) intentionally worked to increase the number of medically unnecessary tests referred by physicians and billed to payors like Allstate.

252. First, Total Toxicology’s requisition form allowed treating providers to select a predetermined custom profile or panel preference (and if no selection was made, a preselected testing option would be performed) that mandated that the full slate of drugs/analytes contained therein would be tested every time the referring provider referred a urine sample to Total Toxicology without any patient-specific consideration. *See Exhibit 8* (a representative requisition form).

253. Second, Total Toxicology’s requisition form did not allow referring providers to remove specific drugs/analytes from the selection of panel preferences, but rather only to choose additional tests.

254. The OIG has also stated that “when claims for medically unnecessary services are discovered, Medicare holds the billing laboratory financially responsible for any incorrect payments.” *See Exhibit 24 at p. 18* (emphasis added).

255. The defendants submitted claims for medically unnecessary urine drug testing; thus, Total Toxicology is financially responsible for all payments made by Allstate.

256. Furthermore, Bluth submitted a generic letter falsely attesting to the “medical necessity” of the urine drug testing, meaning that the defendants cannot lay blame for the excessive testing at the feet of the referring physician. *See Exhibit 1.*

257. For all of these reasons, the requisition forms and panel preferences developed and used by the defendants facilitated and encouraged excessive and unnecessary urine drug testing.

258. A competitor to Total Toxicology in the urine drug testing market recently agreed to pay the government almost a quarter of a billion dollars to resolve very similar allegations that standing order and requisition forms were utilized to facilitate unnecessary testing, including the following specific allegations:

- a. “A core element of Millennium’s business model was the use of physician standing order forms. Millennium created the forms as part of its plan to direct physicians to establish protocols for laboratory testing to be performed on all of their patients – usually, at a minimum, a dozen or more drug tests – regardless

of each patient's individualized need and condition." *See*

Exhibit 2, ¶ 88.

- b. "Millennium expected not only that physicians would have a Standing Order or Custom Profile, but also required certain testing thresholds, so that Millennium could make more money. Millennium refused to do business with accounts that failed to meet these thresholds." Id. at ¶ 95.
- c. "Millennium employees routinely submitted completed Custom Profile forms to headquarters for processing . . . and often filled out information on the Custom Profile forms themselves." Id. at ¶ 98 (internal citation omitted).
- d. "Millennium even processed specimens under customers' Custom Profiles in instances where the 'Use Custom Profile' box in Section A of the requisition form was left blank." Id. at ¶ 99.

See Exhibit 3.

259. Total Toxicology billed Allstate for urine drug testing that was ordered pursuant to a previously-filed custom profile or panel preference relating to more than 90% of the patients at issue in this Complaint.

260. Allstate is not required to reimburse Total Toxicology for urine drug testing that is not patient-specific and that is unnecessary.

261. Allstate is entitled to a return of monies it paid to Total Toxicology for these medically unnecessary urine drug tests.

D. DEFENDANTS ADDED DIAGNOSIS CODES TO FALSELY SUPPORT THEIR BILLS FOR URINE DRUG TESTING

262. According to HIPAA, physicians are required to use International Classification of Disease (“ICD”) codes to identify the diagnoses of patients.

263. Effective October 1, 2015, ICD-9 codes were replaced by ICD-10 codes.

264. ICD-9 codes were the 9th Edition of ICD codes and ICD-10 codes are the 10th Edition.

265. A patient’s diagnosis and ICD diagnosis code can only be determined by his or her treating physician.

266. Almost every patient at issue in this Complaint was diagnosed by his or her treating provider with “chronic pain due to trauma” or another “pain”-related diagnosis, identified by the corresponding ICD-9 or ICD-10 code.

267. However, Total Toxicology submitted bills to Allstate that included v58.69, a diagnosis code that indicates a patient was diagnosed with “long-term (current) use of other medications” and Z79.899, a diagnosis code that indicates a patient was diagnosed with “other long term (current) drug therapy.”

268. The v58.69 and Z79.899 diagnoses were not made by the doctors actually treating the patients, but rather were added by the defendants (none of whom treated or even saw a single patient at issue in this Complaint) solely because they believed the addition of such diagnoses on the bills would increase the likelihood that their bills would be paid by Allstate.

269. Each instance that Total Toxicology submitted a bill to Allstate that contained diagnosis code v58.69 (“*long-term (current) use of other medications*”) or Z79.899 (“*other long term (current) drug therapy*”) not originally identified by the referring provider, is an individual misrepresentation by the defendants to falsely justify the urine drug testing at issue.

270. Attached hereto at Exhibit 25 is a complete listing of each patient for whom the defendants falsely made their own diagnosis and included an additional diagnosis code in the bill submitted to Allstate.

271. The reason for the misrepresentation of diagnosis codes is simple: the defendants used any means, including the misrepresentation of a treating provider’s diagnosis of patients at issue in this Complaint, to increase their profits.

272. Each instance identified in Exhibit 25 is an instance in which Total Toxicology intentionally deceived Allstate.

1. Exemplar Claims

273. The following are representative examples of the defendants' practice of adding an ICD-9 or ICD-10 diagnosis code to bills submitted to Allstate through the U.S. Mail to falsely justify the urine drug testing at issue in this Complaint.

a. Patient K.J. (Claim No. 0337600670)

274. Patient K.J. presented to Mendelson Orthopedics on August 27, 2015 and purportedly gave a urine sample to Hall.

275. Mendelson Orthopedics submitted a requisition form with K.J.'s purported urine specimen to Total Toxicology that indicated K.J. was diagnosed with ICD-9 code 338.21 ("*Chronic pain due to trauma*") with no secondary diagnosis identified. *See Exhibit 26.*

276. In fact, Total Toxicology's requisition form has a preprinted section that allows a referring provider to write in the primary diagnosis of each patient and then check off a list of three (3) predetermined secondary diagnosis codes, if applicable. *Id.*

277. Hall, K.J.'s listed referring physician, did not indicate that any of the three (3) predetermined secondary diagnosis codes applied to K.J., including v58.69 ("*Long term use of opioid medication*"). *Id.*

278. Thus, if Mendelson Orthopedics had in fact made a diagnosis of v58.69, it need only have checked off a box to so indicate.

279. Instead, the v58.69 diagnosis was added by the defendants without any determination from K.J.'s treating healthcare professional.

280. Total Toxicology submitted a HICF to Allstate through the U.S. Mail for the urine drug testing services encompassed by the following twenty-three (23) billing codes: 80324 (amphetamines); 80345 (barbiturates); 80346 (benzodiazepines); 80348 (buprenorphine); 80353 (cocaine); 80361 (opiates); 80369 (skeletal muscle relaxants); 80356 (heroin metabolite); 80359 (Methylenedioxymphetamines (MDA, MDEA, MDMA)); 80362 (opioids and opiate analogs); 80358 (methadone); 80354 (fentanyl); 80366 (pregabalin); 80372 (tapentadol); 80373 (tramadol); 80355 (gabapentin); 80360 (methylphenidate); 83992 (PCP); 80365 (oxycodone); 81003 (urinalysis); 82570 (creatinine); 83986 (pH; body fluid); and 84311 (spectrophotometry). *See Exhibit 27.*

281. In an attempt to falsely justify the medically unnecessary urine drug testing billed for, Total Toxicology submitted a bill to Allstate through the U.S. Mail that included ICD-9 code v58.69, a diagnosis not made by Hall, K.J.'s treating provider. *Id.*

282. Furthermore, Bluth submitted a signed medical necessity letter to Allstate to falsely support Total Toxicology's charges for its urine drug testing of K.J.'s urine specimen.

283. Allstate was billed \$1,870.89 relative to these twenty-three (23) urine drug testing CPT Codes that were falsely justified by the defendants when they included an additional diagnosis code that was not identified by K.J.'s referring physician. Id.

284. Total Toxicology and Bluth submitted claims for payment and accompanying medical records relative to K.J. to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary and falsely justified.

285. Allstate relied upon Total Toxicology's and Bluth's submissions in adjusting the claims.

b. Patient P.P. (Claim No. 0336453030)

286. Patient P.P. presented to Mendelson Orthopedics on June 24, 2015 and purportedly gave a urine sample to Paese.

287. Mendelson Orthopedics submitted a requisition form with P.P.'s purported urine specimen to Total Toxicology that failed to indicate a diagnosis code for P.P. *See Exhibit 28.*

288. In fact, Total Toxicology's requisition form has a preprinted section that allows a referring provider to write in the primary diagnosis of each patient and then check off a list of three (3) predetermined secondary diagnosis codes, if applicable. Id.

289. Paese, P.P.'s listed treating physician, did not indicate a primary diagnosis code or select any of the three (3) predetermined secondary diagnosis codes applied to P.P., including v58.69 ("Long term use of opioid medication").

Id.

290. Total Toxicology submitted a HICF to Allstate through the U.S. Mail for the urine drug testing services encompassed by the following twenty-three (23) billing codes: 80324 (amphetamines); 80345 (barbiturates); 80346 (benzodiazepines); 80348 (buprenorphine); 80353 (cocaine); 80361 (opiates); 80369 (skeletal muscle relaxants); 80356 (heroin metabolite); 80359 (Methylenedioxymphetamines (MDA, MDEA, MDMA)); 80362 (opioids and opiate analogs); 80358 (methadone); 80354 (fentanyl); 80366 (pregabalin); 80372 (tapentadol); 80373 (tramadol); 80355 (gabapentin); 80360 (methylphenidate); 83992 (PCP); 80365 (oxycodone); 81003 (urinalysis); 82570 (creatinine); 83986 (pH; body fluid); and 84311 (spectrophotometry). *See Exhibit 29.*

291. In an attempt to falsely justify the medically unnecessary urine drug testing performed on P.P.'s specimen, Total Toxicology submitted a bill to Allstate through the U.S. Mail that included ICD-9 code v58.69, a diagnosis code not made by Paese, P.P.'s treating provider. Id.

292. Furthermore, Bluth submitted a signed medical necessity letter to Allstate to falsely support Total Toxicology's charges for its urine drug testing of P.P.'s urine specimen.

293. Allstate was billed \$1,665.85 relative to these twenty-three (23) urine drug testing CPT Codes that were falsely justified by the defendants when they included an additional diagnosis code that was not identified by P.P.'s referring physician. Id.

294. Total Toxicology and Bluth submitted claims for payment and accompanying medical records relative to P.P. to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary and falsely justified.

295. Allstate relied upon Total Toxicology's and Bluth's submissions in adjusting the claims.

c. Patient R.O. (Claim No. 0375137775)

296. Patient R.O. presented to Mendelson Orthopedics on October 12, 2015 and purportedly gave a urine sample to Paese.

297. Mendelson Orthopedics submitted a requisition form with R.O.'s purported urine specimen to Total Toxicology that indicated R.O. was diagnosed with 338.21 and G89.21, both of which represent a diagnosis of “[c]hronic pain due to trauma,” with no secondary diagnosis identified. *See Exhibit 30.*

298. In fact, Total Toxicology's requisition form has a preprinted section that allows a referring provider to write in the primary diagnosis of each patient and then check off a list of three (3) predetermined secondary diagnosis codes, if applicable. Id.

299. Paese, R.O.'s treating physician, did not indicate that any of the three (3) predetermined secondary diagnosis codes applied to R.O. Id.

300. Instead, the diagnosis code Z79.899 ("Other long term (current) drug therapy") was added by the defendants without any determination from K.J.'s treating healthcare professional.

301. Total Toxicology submitted a HICF to Allstate through the U.S. Mail for the urine drug testing services encompassed by the following twenty-four (24) billing codes: 80324 (amphetamines); 80345 (barbiturates); 80346 (benzodiazepines); 80348 (buprenorphine); 80353 (cocaine); 80361 (opiates); 80369 (skeletal muscle relaxants); 80356 (heroin metabolite); 80359 (Methylenedioxymphetamines (MDA, MDEA, MDMA)); 80362 (opioids and opiate analogs); 80358 (methadone); 80354 (fentanyl); 80366 (pregabalin); 80372 (tapentadol); 80373 (tramadol); 80355 (gabapentin); 80360 (methylphenidate); 83992 (PCP); 80365 (oxycodone); 81003 (urinalysis); 82570 (creatinine); 83986 (pH; body fluid); 84311 (spectrophotometry); and 82492 (multiple analytes). See Exhibit 31.

302. However, in an attempt to falsely justify the medically unnecessary urine drug testing performed on R.O.’s specimen, the defendants submitted a bill to Allstate through the U.S. Mail that included ICD-10 code Z79.899 (“*Other long term (current) drug therapy*”), a diagnosis code not identified by Paese. Id.

303. Furthermore, Bluth submitted a signed medical necessity letter to Allstate to falsely support Total Toxicology’s charges for its urine drug testing of R.O.’s urine specimen.

304. Allstate was billed \$1,934.42 relative to these twenty-four (24) urine drug testing CPT Codes that were falsely justified by the defendants when they included an additional diagnosis code that was not identified by R.O.’s referring physician. Id.

305. Total Toxicology and Bluth submitted claims for payment and accompanying medical records relative to R.O. to Allstate through the U.S. Mail seeking reimbursement for testing services that were medically unnecessary and falsely justified.

306. Allstate relied upon Total Toxicology’s and Bluth’s submissions in adjusting the claims.

VIII. FRAUDULENT BILLING PRACTICES

307. Providers like Total Toxicology have a responsibility to select and submit the billing code that accurately and truthfully identifies the services performed and the complexity involved in rendering those services.

308. Total Toxicology, by and through the individual defendants, failed to meet its responsibility and instead submitted demands for payment to Allstate for (1) quantitative testing that was not performed, (2) unnecessary quantitative testing, and (3) testing that was not specifically ordered by the provider.

309. Total Toxicology submitted claims to Allstate through the U.S. Mail for testing billed in direct violation of the CPT Code Book and the AMA.

310. Total Toxicology also submitted claims to Allstate through the U.S. Mail for testing billed using the fraudulent billing practice of unbundling, a practice used to increase the amount charged for each specimen purportedly tested.

A. SPECIMEN VALIDITY TESTING UNBUNDLED

311. Specimen validity testing is the evaluation of a specimen to determine if it is consistent with normal human urine.

312. Total Toxicology performed specimen validity testing on each specimen it received. *See Exhibit 4.*

313. Total Toxicology consistently billed Allstate using CPT Codes 81003 (Urinalysis); 82570 (Creatinine); 83986 (pH); and 84311 (Spectrophotometry)

each time Total Toxicology purportedly performed specimen validity testing on a specimen it received from its referring client physicians.

314. However, only CPT Codes 81003 and 82570 were appropriate billing codes for Total Toxicology to bill for its specimen validity testing (assuming the specimen validity testing was ordered by the referring physician and medically necessary).

315. CPT Code 81003 is an all-encompassing urinalysis code that includes testing for “bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, **pH**, protein, **specific gravity**, urobilinogen, any number of these constituents; automated, without microscopy” (emphasis added).

316. CPT Code 82570 indicates that testing for “urine creatinine” was performed on the specimen.

317. Total Toxicology unbundled CPT Codes 83986 and 84311 from CPT Code 81003 when it submitted its specimen validity claims to Allstate.

318. CPT Codes 83986 and 84311 both represent testing components that are covered by the all-inclusive 81003 billing code.

319. Moreover, CPT Codes 83986 and 84311 are not appropriate for inclusion in urine specimen validity testing because they are both meant to be used for the testing of bodily fluids other than urine.

320. Specifically, CPT Code 83986 states that it is to be used when testing for “pH [of a] body fluid, not otherwise specified” and CPT Code 84311 is to be used for “spectrophotometry [for] analyte not elsewhere specified” (testing for spectrophotometry or specific gravity).

321. The terms “not otherwise specified” and “not elsewhere specified” indicate that CPT Codes 83986 and 84311, respectively, are only to be billed for tests on fluids or analytes not already referenced in a specific CPT Code.

322. Specific Gravity and pH testing on urine specimens are specifically covered by the all-inclusive CPT Code 81003.

323. Each and every instance of Total Toxicology’s billing Allstate CPT Codes 83986 and 84311 during the same date of service as CPT Code 81003 constitutes two separate instances of unbundling.

324. The prevalence of the defendants’ unbundling in this regard evidences that it was a regular practice that was knowingly and intentionally done.

325. Unbundling that is done knowingly and intentionally constitutes a fraudulent billing practice.

B. MULTIPLE UNITS BILLED FOR CODES DEFINED AS “EACH PROCEDURE”

326. Total Toxicology submitted bills to Allstate seeking payment for multiple units of billing code G6056 (“*Opiate(s), drug and metabolites, each procedure*”) in violation of established billing guidelines.

327. By its definition, code G6056 can only be billed once per “procedure.”

328. Total Toxicology admits that its most prevalent urine drug testing methodology (LC-MS/MS) consists of a single test (i.e., procedure) that is capable of generating numerous drug-specific results.

329. According to Total Toxicology’s website, “liquid chromatography tandem mass-spectrometry (LC-MS/MS), is a more specific method, and returns a quantitative analytical result. These results provide precise identification of **all drugs and metabolites present or absent.**” *See Exhibit 5* (emphasis added).

330. In other words, Total Toxicology performs one procedure on each specimen it receives and reports the results generated by this one test.

331. Because Total Toxicology is capable of performing one test (procedure) on a specimen to identify all drugs present under the opiate drug class, billing multiple units of billing code G6056 for the same date of service for the same patient is improper and misrepresents the testing performed by Total Toxicology.

332. The defendants submitted several charges using code G6056 falsely claiming that multiple testing procedures were performed on patients at issue in this Complaint, including the following:

| Claim Number | Patient Initials | Date of Service | CPT Code Billed | CPT Code Description | Units Billed | Billed Amount |
|---------------------|-------------------------|------------------------|------------------------|--|---------------------|----------------------|
| 0339173643 | T.S. | 1/29/2015 | G6056 | Opiate(s), drugs and metabolites, each procedure | 7 | \$445.83 |
| 0347481178 | H.R. | 2/18/2015 | G6056 | Opiate(s), drugs and metabolites, each procedure | 4 | \$254.76 |
| 0347481178 | H.R. | 7/14/2015 | G6056 | Opiate(s), drugs and metabolites, each procedure | 4 | \$254.76 |
| 0347481178 | H.R. | 7/27/2015 | G6056 | Opiate(s), drugs and metabolites, each procedure | 4 | \$254.76 |
| 0392556858 | N.H. | 10/12/2015 | G6056 | Opiate(s), drugs and metabolites, each procedure | 4 | \$254.76 |
| 2173181096 | R.H. | 1/30/2015 | G6056 | Opiate(s), drugs and metabolites, each procedure | 7 | \$445.83 |

IX. SPECIFIC ALLEGATIONS OF MISREPRESENTATIONS MADE TO AND RELIED ON BY ALLSTATE

A. MISREPRESENTATIONS BY THE DEFENDANTS

333. To induce Allstate to pay promptly their fraudulent charges for (1) tests not actually rendered, (2) unnecessary testing, and (3) fraudulently-billed testing, the defendants submitted or caused to be submitted to Allstate documentation, including but not limited to bills, invoices, medical records (lab reports), and the medical necessity letter signed by Bluth, that materially misrepresented that the drug testing performed was actually provided and was medically necessary as required by the Michigan No-Fault.

334. As discussed throughout this pleading, the full extent of misrepresentations contained in the HICFs/bills submitted to Allstate by the defendants only became known to Allstate upon its investigation of the defendants, including discovery of the number of drugs/drug classes contained in each panel

preference and the defendants' refusal to permit referring providers to request that only necessary urine drug testing be done.

335. None of these facts is evident within the four corners of the documents submitted to Allstate by the defendants and upon which Allstate relied in adjusting the claims and tendering payment.

336. Total Toxicology also withheld the reverse side of the requisition form from Allstate, although each requisition form states "PLEASE SEE REVERSE SIDE FOR IMPORTANT NOTES," a tactic that prohibited Allstate from knowing what specific drugs were at issue.

337. Claims under the Michigan No-Fault Act can only be submitted for reasonably necessary services for an injured person's care, recovery, or rehabilitation.

338. Thus, every time Total Toxicology, at the direction of its officers and managers Bluth, Zack, and Mann, submitted bills and lab reports to Allstate supporting its claims for No-Fault benefits, the defendants necessarily warranted that such bills and medical records related to necessary testing that was actually performed.

339. In fact, however, the urine drug testing billed for by Total Toxicology (at the direction of Bluth, Zack, and Mann) was rarely necessary, including several

tests that were done without a determination of medical necessity by a licensed healthcare provider.

340. The full extent of the defendants' fraudulent acts – including billing for performing unnecessary and excessive confirmation testing and using fraudulent billing practices – was not and could not have been known to Allstate until it commenced its investigation of the defendants shortly before filing this Complaint.

341. In particular, the defendants took advantage of the technical complexity and esoteric nature of the urine drug testing Total Toxicology allegedly performed to mask their fraudulent billing.

342. Moreover, Allstate is obligated to pay or deny claims received from providers within a small period of time.

343. As such, and given the number of bills received by Allstate every day, Allstate cannot scrutinize every bill it receives and must at times rely on the submitting provider to comply with the law and submit only valid claims for No-Fault benefits.

344. This is particularly true where the provider (here, Total Toxicology) submits claims for specialized services such as clinical laboratory urine drug testing, which requires a level of expertise to perform and bill for that exceeds the knowledge of the typical insurance claims adjuster.

345. The fact of billing for unnecessary and excessive urine drug testing is present with respect to every claim at issue herein.

346. Thus, each claim for payment (and accompanying medical records) under Michigan's No-Fault Act sent to Allstate by or at the direction of the defendants constitutes a misrepresentation because the treatment underlying the claim was not medically necessary, which it must be in order for a service to be compensable under Michigan law.

347. The urine drug testing rendered by, and at the direction of, the defendants was not lawful and every claim for payment submitted to Allstate through the U.S. Mail misrepresented this fact.

348. Moreover, each bill submitted to Allstate by or on behalf of the defendants contained the following notation: "NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."

349. Through the submission of lab reports, invoices, bills, Bluth's letters of medical necessity, and other medical documentation to Allstate via the U.S. Mail, the defendants attested to the fact and medical necessity of the drug testing for which they billed Allstate.

350. As the defendants did not render reasonably necessary drug testing and engaged in fraudulent billing practices, each bill and accompanying documentation submitted by Total Toxicology (at the direction and with the knowledge of its officers and managers Bluth, Katz, and Mann) to Allstate constitutes a material misrepresentation.

351. Bluth is Total Toxicology's Chief Medical Officer and the person who signed letters submitted to Allstate attesting to the medical necessity of the urine drug testing at issue herein.

352. As a licensed medical professional, Bluth was obligated, legally and ethically, to act honestly, with integrity, and in accordance with his professional oaths and pledges.

353. As a licensed healthcare professional, Zack was obligated, legally and ethically, to act honestly, with integrity, and in accordance with his professional oaths and pledges.

354. Mann is the manager of Total Toxicology and also charged with overseeing the entire company, including its standard testing and billing procedures.

355. As the individuals in charge of and responsible for Total Toxicology, Bluth, Zack, and Mann are directly responsible for the misrepresentations made to Allstate by Total Toxicology.

356. Bluth, Zack, and Mann managed and operated every aspect of Total Toxicology from establishing the pattern and protocol whereby urine samples were tested for as many drugs as possible regardless of the necessity of such testing, to permitting Total Toxicology to lie about the tests it performed, to encouraging fraudulent billing practices designed solely to increase the amount billed to Allstate.

357. As the managers and operators of Total Toxicology, Bluth, Zack, and Mann ordered and facilitated the misrepresentations made to Allstate.

358. Each misrepresentation made by Bluth and Zack was also in violation of their legal and ethical obligations as healthcare professionals.

B. ALLSTATE'S JUSTIFIABLE RELIANCE

359. At all relevant times, the defendants concealed from Allstate the truth regarding the fact and medical necessity of urine drug testing allegedly performed to prevent Allstate from discovering that the claims submitted by Total Toxicology were not compensable under Michigan's No-Fault Act.

360. These misrepresentations include submitting false medical documentation, including bills, documenting the fact and necessity of urine drug testing in order to seek No-Fault benefits reimbursement.

361. Moreover, Bluth himself submitted medical necessity letters to Allstate verifying that Total Toxicology performed only necessary urine drug testing.

362. Evidence of the fraudulent scheme detailed herein was not discovered until after patterns had emerged and Allstate began to investigate Total Toxicology and the individual defendants, revealing the true nature and full scope of the defendants' fraudulent scheme.

363. The defendants utilized their superior knowledge of the complex and specialized testing methodologies and billing practices associated with urine drug testing to mask the depth and breadth of their fraudulent billing scheme.

364. Due to the defendants' material misrepresentations and other affirmative acts designed to conceal their fraudulent scheme from Allstate, Allstate did not and could not have discovered that its damages were attributable to fraud until shortly before filing the within Complaint.

365. In reasonable reliance on the defendants' misrepresentations, Allstate paid money to Total Toxicology to its detriment.

366. Allstate would not have paid these monies had the defendants provided true and accurate information about the fact and necessity of the drug testing provided.

367. As a result, Allstate has paid in excess of \$15,802 in reasonable reliance on the false medical documentation and false representations regarding Total Toxicology's eligibility for reimbursement under Michigan's No-Fault Act.

X. SPECIFIC ALLEGATIONS OF MAIL FRAUD RACKETEERING ACTIVITY

368. As discussed above, the defendants devised and agreed to enact a scheme to defraud Allstate by billing for unnecessary and excessive urine drug testing.

369. The drug testing purportedly provided by Total Toxicology was fraudulent because (a) it was not actually performed, (b) it resulted from improper referral relationships between the defendants and the referring provider, (c) it was performed pursuant to a custom profile/panel preference and not based on patients' individual clinical needs, and (d) it was billed using several improper billing practices, including unbundling.

370. Despite knowing that Total Toxicology's services were medically unnecessary and improperly billed, and therefore not compensable under Michigan's No-Fault Act, the defendants nonetheless submitted or caused to be submitted reimbursement claims to Allstate through the U.S. Mail seeking No-Fault benefit payments.

371. The objective of the scheme to defraud Allstate, which occurred throughout the period noted in Exhibits 4 and 32, was to collect No-Fault benefits

to which the defendants were not entitled because the medical services rendered, if at all, were not necessary and also because the defendants engaged in fraudulent billing practices.

372. This objective necessarily required the submission of claims to Allstate.

373. The defendants created, prepared, and submitted false medical documentation and placed the same in a post office and/or authorized depository for mail to be sent and delivered by the United States Postal Service.

374. All lab reports, documents, medical records, notes, bills, correspondence, medical necessity letters signed by Bluth, and requests for payment in connection with the insurance claims referenced throughout this pleading traveled through the U.S. Mail.

375. Every automobile insurance claim detailed herein involved at least one use of the U.S. Mail, including the mailing of, among other things, the notice of claim, initial policies, insurance payments, medical records, bills, claims settlement checks, and return of the cancelled settlement drafts to the financial institution(s) from which the draft(s) were drawn, as well as the return of settlement draft duplicates to the insurance carrier for filing.

376. The fraudulent medical billing scheme detailed herein generated hundreds of mailings.

377. A chart highlighting representative examples of mail fraud arising from the defendants' patient/business files is annexed hereto at Exhibit 32.

378. As detailed herein, the defendants also submitted, caused to be submitted, or knew medical documentation and claims for payment would be submitted to Allstate related to each exemplar patient discussed in this Complaint.

379. Bluth is Total Toxicology's Chief Medical Officer and the person who signed letters submitted to Allstate attesting to the medical necessity of the urine drug testing at issue herein.

380. Thus, Bluth, by and through his relationship with Total Toxicology, mailed or caused to be mailed documents, including lab reports, records, and bills, that materially misrepresented that Total Toxicology was (1) providing tests that were necessary, (2) providing tests that were specifically ordered by a physician, and (3) using the proper billing codes for the tests purportedly performed.

381. Zack, as Total Toxicology's President and Chief Financial Officer, was likewise aware of and responsible for the misrepresentations contained in the medical documentation and bills mailed to Allstate.

382. Mann, as Total Toxicology's manager, established and endorsed the testing and billing practices implemented and utilized by Total Toxicology, including misrepresenting the urine drug tests that were actually done and the necessity of all testing.

383. The defendants knew, and it was reasonably foreseeable, that Total Toxicology would submit false medical documentation, including the representative mailings detailed in Exhibit 32 annexed hereto, for No-Fault benefits reimbursement through the U.S. Mail related to the urine drug testing allegedly performed by Total Toxicology.

384. Indeed, it was within the ordinary course of business for Total Toxicology to submit claims for No-Fault benefits reimbursement to insurance carriers like Allstate through the U.S. Mail.

385. As the defendants agreed that Total Toxicology would use (and, in fact, did use) the mails in furtherance of their scheme to defraud Allstate by seeking payment for drug testing that was not compensable under Michigan's No-Fault Act, these defendants committed mail fraud, as defined in 18 U.S.C. § 1341.

386. A chart detailing representative examples of the mail fraud agreed to and perpetrated by the defendants is attached hereto at Exhibit 32 and includes specific information regarding the date, the sender, the recipient, and the content of such mailings.

387. As discussed above, the representative mailings identified in Exhibit 32 contained misrepresentations regarding the fact, lawfulness, and necessity of the drug testing for which Allstate was billed.

388. The defendants continue to submit misrepresentation-laden bills and medical records to Allstate through the U.S. Mail, as the same constitutes the way they conduct their ongoing business.

389. Allstate reasonably relied on the submissions it received from the defendants through the U.S. Mail when adjusting the claims and tendering payment, including those representative submissions set out in Exhibit 32 and discussed as exemplar claims *supra*.

390. These payments were shared directly by all the defendants named herein.

391. As the defendants agreed to pursue the same criminal objective (namely, mail fraud), they committed a conspiracy within the meaning of the RICO Act, 18 U.S.C. § 1962(d), and are therefore jointly and severally liable for Allstate's damages.

XI. DAMAGES

392. The pattern of fraudulent conduct by the defendants injured Allstate in its business and property by reason of the aforesaid violations of law.

393. Although it is not necessary for Allstate to calculate damages with specificity at this stage in the litigation, and Allstate's damages continue to accrue, Allstate's injury includes, but is not limited to, compensatory damages in excess of \$15,802.

394. Exhibit 33, annexed hereto and incorporated herein as if fully set forth in their entirety, identify monies paid by Allstate to Total Toxicology by date, payor, payee, patient claim number, check number, and amount.

395. Allstate's claim for compensatory damages, as set out in Exhibit 33, does not include payment made with respect to any Assigned Claim Facility claimant.

396. Allstate also seeks damages, in an amount to be determined at trial, related to the cost of investigation to uncover the fraudulent activities of the defendants and the cost of claims handling for claims submitted by Total Toxicology.

XII. CAUSES OF ACTION

COUNT I
VIOLATION OF 18 U.S.C. § 1962(c)
(Total Toxicology Labs, LLC Enterprise)
Against Martin Bluth, M.D., Scott P. Zack, D.C., and Cory J. Mann

397. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 to 396 set forth above as if fully set forth herein.

398. Total Toxicology constitutes an enterprise, as defined in 18 U.S.C. § 1961(4), engaged in, and the activities of which affect, interstate commerce.

399. In connection with each of the claims identified in the within Complaint and the exhibits hereto, Martin Bluth, M.D., Scott P. Zack, D.C., and Cory J. Mann (collectively, the "Count I defendants") intentionally caused to be

prepared and mailed false medical documentation by Total Toxicology, or knew that such false medical documentation would be mailed in the ordinary course of Total Toxicology's business, or should have reasonably foreseen that the mailing of such false medical documentation by Total Toxicology would occur, in furtherance of the Count I defendants' scheme to defraud.

400. The Count I defendants employed, knew, or should have foreseen that two or more mailings to demand and/or receive payment from Allstate on certain dates, including but not limited to those dates identified in the chart annexed hereto at Exhibit 32.

401. Among other things, lab reports, letters of medical necessity, medical records, bills, and invoices were delivered to Allstate thought the U.S. Mail.

402. Policies of insurance were delivered to insureds through the U.S. Mail.

403. Payments to Total Toxicology from Allstate were transmitted through the U.S. Mail.

404. As documented above, the Count I defendants repeatedly and intentionally submitted, caused to be submitted, or knew that documentation would be submitted to Allstate for urine drug testing that was purportedly performed by Total Toxicology to collect payment from Allstate under the personal injury

protection benefits portion of the Allstate policies and applicable provisions of the Michigan No-Fault Act.

405. As a result of, and in reasonable reliance on, these misleading documents and misrepresentations, Allstate, by its agents and employees, issued drafts to Total Toxicology for the benefit of the Count I defendants that would not otherwise have been paid.

406. The Count I defendants' pattern of submitting, causing to be submitted, or knowing that fraudulent claims that appeared legitimate on their face would be submitted prevented Allstate from discovering the fraudulent scheme for a long period of time, thus enabling the defendants to continue their fraudulent scheme without detection.

407. The acts set forth above constitute indictable offenses pursuant to 18 U.S.C. §1341 (mail fraud).

408. By mailing, or agreeing that the mails would be used to submit, numerous fraudulent claims in an ongoing scheme, the defendants engaged in a pattern of racketeering activity within the meaning of 18 U.S.C. § 1962(c).

409. The activities alleged in this Complaint had the direct effect of causing funds to be transferred from Allstate to Total Toxicology for the benefit of the Count I defendants.

410. The Count I defendants participated in the conduct of the Total Toxicology enterprise through a pattern of racketeering activities.

411. Allstate is a “person,” as defined by 18 U.S.C. § 1961(3), injured in its business or property by reason of the Count I defendants’ fraudulent acts.

412. The Count I defendants’ conduct in violation of 18 U.S.C. § 1962(c) was the direct and proximate cause of Allstate’s injury.

413. Allstate is in the business of writing insurance and paying claims.

414. Insurance fraud schemes like the one detailed herein have a deleterious impact on Allstate’s overall financial well-being and adversely affect insurance rates.

415. By virtue of the Count I defendants’ violations of 18 U.S.C. § 1962(c), Allstate is entitled to recover from them three times the damages sustained by reason of the claims submitted, caused to be submitted, or known to be submitted, by them, and others acting in concert with them, together with the costs of suit, including reasonable attorney’s fees.

COUNT II
VIOLATIONS OF 18 U.S.C. § 1962(d)
(Total Toxicology Labs, LLC Enterprise)
Against Martin Bluth, M.D., Scott P. Zack, D.C., and Cory J. Mann

416. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 396 set forth above as if fully set forth herein.

417. Defendants Martin Bluth, M.D., Scott P. Zack, D.C., and Cory J. Mann (collectively, the “Count II defendants”) conspired with each other to violate 18 U.S.C. §1962(c) through the facilitation of the operation of Total Toxicology.

418. The Count II defendants each agreed to further, facilitate, support, and/or operate the Total Toxicology enterprise.

419. As such, the Count II defendants conspired to violate 18 U.S.C. §1962(c).

420. The purpose of the conspiracy was to obtain No-Fault payments from Allstate by and through Total Toxicology even though Total Toxicology was not eligible to collect No-Fault payments by virtue of its unlawful conduct.

421. The Count II defendants were aware of this purpose and agreed to take steps to meet the conspiracy’s objectives, including the creation and submission to Allstate of insurance claims and medical documents containing material misrepresentations.

422. Allstate has been injured in its business and property by reason of this conspiratorial conduct whereas Allstate has been induced to make No-Fault claim payments as a result of the Count II defendants’ unlawful conduct described herein.

423. By virtue of this violation of 18 U.S.C. §1962(d), the Count II defendants are jointly and severally liable to Allstate and Allstate is entitled to

recover from each three times the damages sustained by reason of the claims submitted by or on behalf of the Count II defendants, and others acting in concert with them, together with the costs of suit, including reasonable attorney's fees.

COUNT III
COMMON LAW FRAUD
Against All Defendants

424. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 396 set forth above as if fully set forth herein.

425. The scheme to defraud Allstate perpetrated by Total Toxicology Labs, LLC, Martin Bluth, M.D., Scott P. Zack, D.C., and Cory J. Mann was dependent upon a succession of material misrepresentations of fact that Total Toxicology was actually and lawfully rendering medically necessary urine drug testing in compliance with the Michigan No-Fault Act and was entitled to collect benefits thereunder.

426. The misrepresentations made by the defendants include, but are not limited to, those material misrepresentations discussed in the exemplar claims and section IX *supra*.

427. The misrepresentations were intentionally made by the defendants in furtherance of their scheme to defraud and deceive Allstate by submitting, causing to be submitted, or knowing that non-compensable claims for payment under the Michigan No-Fault Act would be submitted to Allstate.

428. The defendants' misrepresentations were known to be false and were made for the purpose of inducing Allstate to make payments for claims that are not compensable under relevant provisions of the Michigan No-Fault Act.

429. Allstate justifiably relied upon such material misrepresentations to its detriment in paying numerous non-meritorious bills for medical expenses pursuant to No-Fault insurance claims and in incurring expenses related to the adjustment and processing of claims submitted by the defendants.

430. As a direct and proximate result of the defendants' fraudulent representations and acts arising from the State of Michigan, Allstate has been damaged as previously described herein and as set out in Exhibit 33.

COUNT IV
CIVIL CONSPIRACY
Against All Defendants

431. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 to 396 set forth above as if fully set forth herein.

432. Defendants Total Toxicology Labs, LLC, Martin Bluth, M.D., Scott P. Zack, D.C., and Cory J. Mann ("Count IV defendants") combined and concerted to accomplish the unlawful purpose of defrauding Allstate by submitting claims for reimbursement under the Michigan No-Fault Act to which they were not entitled because they billed for urine drug testing that was not performed, medically unnecessary and excessive, and fraudulently billed.

433. The Count IV defendants worked together to achieve an unlawful purpose (namely, defrauding Allstate for personal gain).

434. This purpose was known to all of the Count IV defendants and intentionally pursued.

435. Despite knowing that the defendants were not entitled to reimbursement under the Michigan No-Fault Act because they billed for urine drug testing that was not performed, medically unnecessary and excessive, and fraudulently billed, the Count IV defendants nonetheless submitted, caused to be submitted, or knew that claims would be submitted (with accompanying false medical documentation) to Allstate seeking payment to the defendants.

436. In reasonable reliance on the false medical documentation submitted by the defendants, Allstate paid certain of the claims submitted.

437. All of the Count IV defendants benefited from the payments wrongfully procured from Allstate.

438. All of the Count IV defendants directly benefited from the payments made to Total Toxicology Labs, LLC.

439. Therefore, the Count IV defendants committed acts that caused damage to Allstate.

440. All of the Count IV defendants actively and intentionally partook in a scheme to defraud Allstate and also encouraged and aided other Count IV

defendants in the commission of acts done for the benefit of all Count IV defendants and to the unjustified detriment of Allstate.

441. Accordingly, all of the Count IV defendants are equally liable for the fraud perpetrated on Allstate pursuant to their conspiracy.

COUNT V
PAYMENT UNDER MISTAKE OF FACT
Against Total Toxicology Labs, LLC

442. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 396 set forth above as if fully set forth herein.

443. Allstate paid the amounts described herein and itemized in Exhibit 33 under a misunderstanding, misapprehension, error, fault, or ignorance of material facts, namely, the scheme to defraud Allstate by misrepresenting the necessity of urine drug testing allegedly provided by Total Toxicology.

444. Allstate sustained damages by paying under a mistake of fact the claims submitted by, or on behalf of Total Toxicology which misrepresented the reasonableness, necessity, and lawfulness of the urine drug testing allegedly rendered by Total Toxicology.

445. Total Toxicology would be unjustly enriched if permitted to retain the payments made to it under the Michigan No-Fault Statute by Allstate under a mistake of fact.

446. Allstate is entitled to restitution from Total Toxicology for all monies paid to and/or received by it from Allstate, as evidenced in Exhibit 33.

COUNT VI
UNJUST ENRICHMENT
Against Total Toxicology Labs, LLC

447. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 396 set forth above as if fully set forth herein.

448. Allstate paid monies to Total Toxicology, including those amounts itemized in Exhibit 33, in response to the claims submitted, or caused to be submitted, by the defendants under Michigan's No-Fault Act in reasonable belief that it was legally obligated to make such payments based upon the defendants' fraudulent misrepresentations.

449. Allstate's payments constitute a benefit which Total Toxicology aggressively sought and voluntarily accepted.

450. Total Toxicology wrongfully obtained payments from Allstate through the fraudulent scheme detailed herein.

451. Total Toxicology has been unjustly enriched by receipt of these wrongfully-obtained payments from Allstate.

452. Total Toxicology's retention of these payments would violate fundamental principles of justice, equity, and good conscience.

COUNT VII
DECLARATORY RELIEF PURSUANT TO 28 U.S.C. § 2201
Against Total Toxicology Labs, LLC

453. Allstate re-alleges, re-pleads, and incorporates by reference paragraphs 1 through 396 set forth above as if fully set forth herein.

454. Total Toxicology Labs, LLC billed for medically unnecessary urine drug testing with respect to the patients at issue in this Complaint.

455. Pursuant to the Michigan No-Fault Act, Mich. Comp. Laws § 500.3101, *et seq.*, an insurer is liable to pay benefits only for reasonable and necessary expenses arising out of a motor vehicle accident. Mich. Comp. Laws §§ 500.3105 and 500.3107.

456. The lack of reasonableness, necessity, and lawfulness are defenses to an insurer's obligation to pay No-Fault benefits arising out of a motor vehicle accident. Mich. Comp. Laws § 500.3107.

457. Where a provider is unable to show that an expense has been incurred for a reasonably necessary product or service arising out of a motor vehicle accident, there can be no finding of a breach of the insurer's duty to pay, and thus no finding of liability with regard to that expense.

458. Allstate is not obligated to pay insurance proceeds for any services that were not rendered and/or that were unnecessary.

459. Where a claimant and/or assignee (such as Total Toxicology) is unable to show that an expense has been incurred for a reasonably necessary product or service arising out of a motor vehicle accident, there can be no finding of a breach of the insurer's duty to pay, and thus no finding of liability with regard to that expense.

460. Total Toxicology continues to submit claims under the Michigan No-Fault Act for unnecessary and/or not rendered services and other claims remain pending with Allstate.

461. Accordingly, Allstate requests a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, declaring that Total Toxicology Labs, LLC billed for urine drug testing that it did not actually perform and which is not compensable under the Michigan No-Fault Act.

462. Allstate also requests a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, declaring that Total Toxicology Labs, LLC provided medically unnecessary drug testing that is not compensable under the Michigan No-Fault Act.

463. As such, Allstate requests a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, that Total Toxicology Labs, LLC has no standing to submit, pursue, or receive assigned No-Fault benefits from Allstate.

XIII. DEMAND FOR RELIEF

WHEREFORE, plaintiffs Allstate Insurance Company and Allstate Property and Casualty Insurance Company respectfully request that judgment enter in their favor, as follows:

COUNT I

VIOLATION OF 18 U.S.C. § 1962(c)

(Total Toxicology Labs, LLC Enterprise)

Against Martin Bluth, M.D., Scott P. Zack, D.C., and Cory J. Mann

- (a) AWARD Allstate its actual and consequential damages against the defendants jointly and severally in an amount to be determined at trial;
- (b) AWARD Allstate treble damages pursuant to 18 U.S.C. § 1964, together with interest, costs, and attorney's fees;
- (c) GRANT Allstate injunctive relief enjoining the defendants from engaging in the wrongful conduct alleged in the within Complaint; and
- (d) GRANT all other relief this Court deems just and proper.

COUNT II

VIOLATIONS OF 18 U.S.C. § 1962(d)

(Total Toxicology Labs, LLC Enterprise)

Against Martin Bluth, M.D., Scott P. Zack, D.C., and Cory J. Mann

- (a) AWARD Allstate its actual and consequential damages against the defendants jointly and severally in an amount to be determined at trial;
- (b) AWARD Allstate treble damages pursuant to 18 U.S.C. § 1964, together with interest, costs, and attorney's fees;

- (c) GRANT Allstate injunctive relief enjoining the defendants from engaging in the wrongful conduct alleged in the within Complaint; and
- (d) GRANT all other relief this Court deems just and proper.

COUNT III
COMMON LAW FRAUD
Against All Defendants

- (a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial;
- (b) AWARD Allstate its costs, including, but not limited to, investigative costs incurred in the detection of the defendants' illegal conduct; and
- (c) GRANT all other relief this Court deems just and proper.

COUNT IV
CIVIL CONSPIRACY
Against All Defendants

- (a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial;
- (b) AWARD Allstate its costs, including, but not limited to, investigative costs incurred in the detection of the defendants' illegal conduct; and
- (c) GRANT all other relief this Court deems just and proper.

COUNT V
PAYMENT UNDER MISTAKE OF FACT
Against Total Toxicology Labs, LLC

- (a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial; and
- (b) GRANT all other relief this Court deems just.

COUNT VI
UNJUST ENRICHMENT
Against Total Toxicology Labs, LLC

- (a) AWARD Allstate its actual and consequential damages in an amount to be determined at trial; and
- (b) GRANT any other relief this Court deems just and proper.

COUNT VII
DECLARATORY RELIEF PURSUANT TO 28 U.S.C. §2201
Against Total Toxicology Labs, LLC

- (a) DECLARE that Total Toxicology Labs, LLC wrongfully submitted bills for urine drug testing that was not actually provided and, therefore, not compensable under the Michigan No-Fault Act;
- (b) DECLARE that Total Toxicology Labs, LLC wrongfully submitted bills for urine drug testing that was not necessary and, therefore, not compensable under the Michigan No-Fault Act;
- (c) DECLARE that the activities of Total Toxicology Labs, LLC were fraudulent;

(d) DECLARE that Allstate has no obligation to pay pending and/or previously-denied No-Fault insurance claims submitted by Total Toxicology Labs, LLC; and

(e) GRANT all other relief this Court deems just and proper.

XIV. JURY TRIAL DEMAND

The plaintiffs hereby demand a trial by jury on all claims.

Respectfully submitted,

SMITH & BRINK

/s/ Richard D. King

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